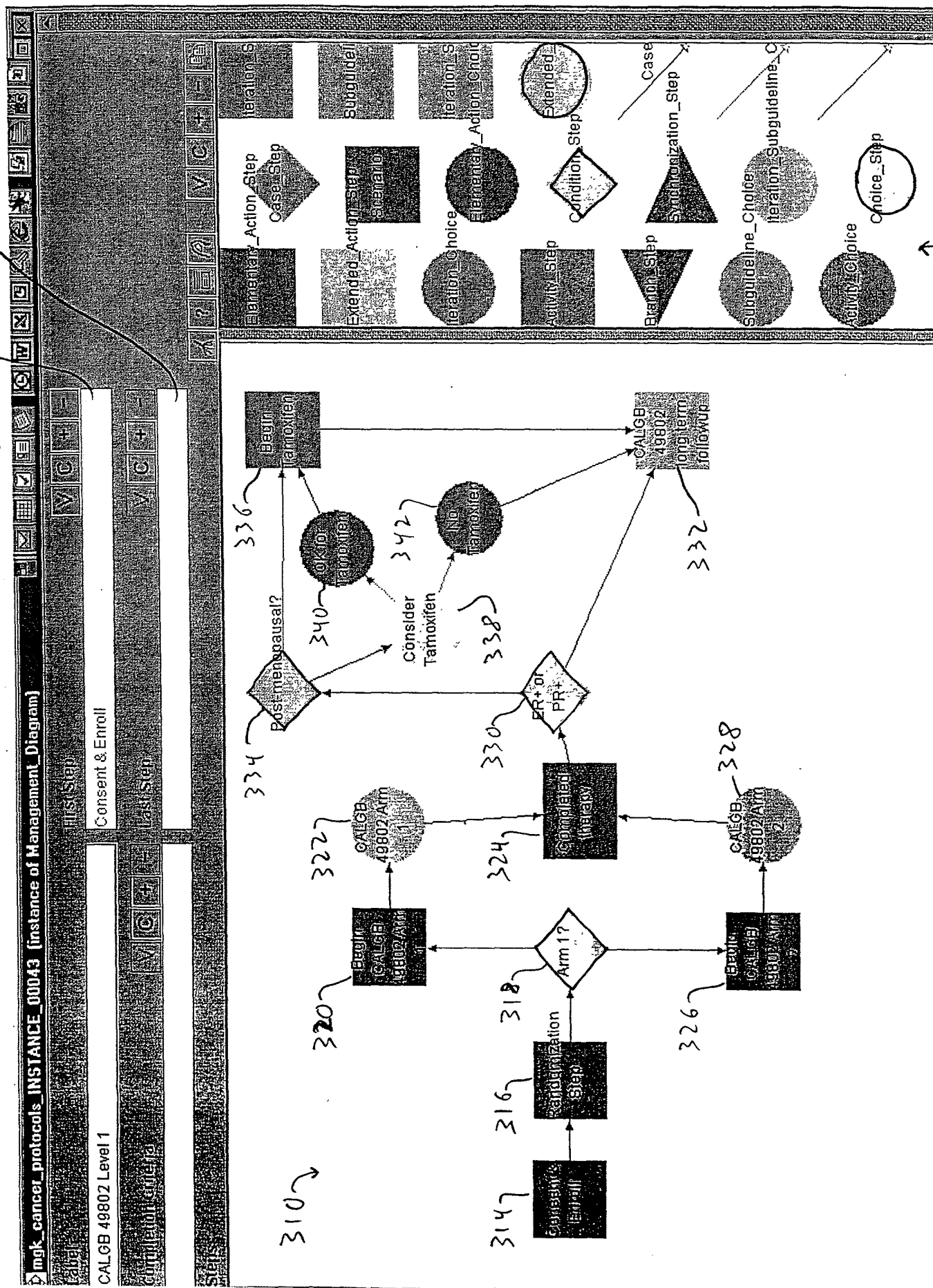


Fig. 1

Label	CALGB 49802	Version	mgk
Title	Phase III Study of Adriamycin/Taxotere vs Adriamycin/Cytoxan for the Adjuvant Treatment of Node Positive or High Risk Node Negative Breast Cancer	Authors	M. G. Public
Clinical Application		Reference	MUSC PRN web page
CALGB 49802 Level 1			
Current Reference			
Entry Criteria (Values)			
Principal Name	CALGB 49802	Inclusion	<input type="checkbox"/> Histology <input type="checkbox"/> 1-3 hist <input type="checkbox"/> No evid <input type="checkbox"/> Absolut <input type="checkbox"/> Platelet <input type="checkbox"/> Left ven <input type="checkbox"/> Bilirubin <input type="checkbox"/> Age 18 <input type="checkbox"/> Effective <input type="checkbox"/> No prior <input type="checkbox"/> No prior <input type="checkbox"/> No conc
Clinical State Name			
Exclusion List	<input type="checkbox"/> Tumor of any size with direct extension to chest wall or skin (T4) <input type="checkbox"/> Patient is pregnant or nursing		

Fig. 2



3511

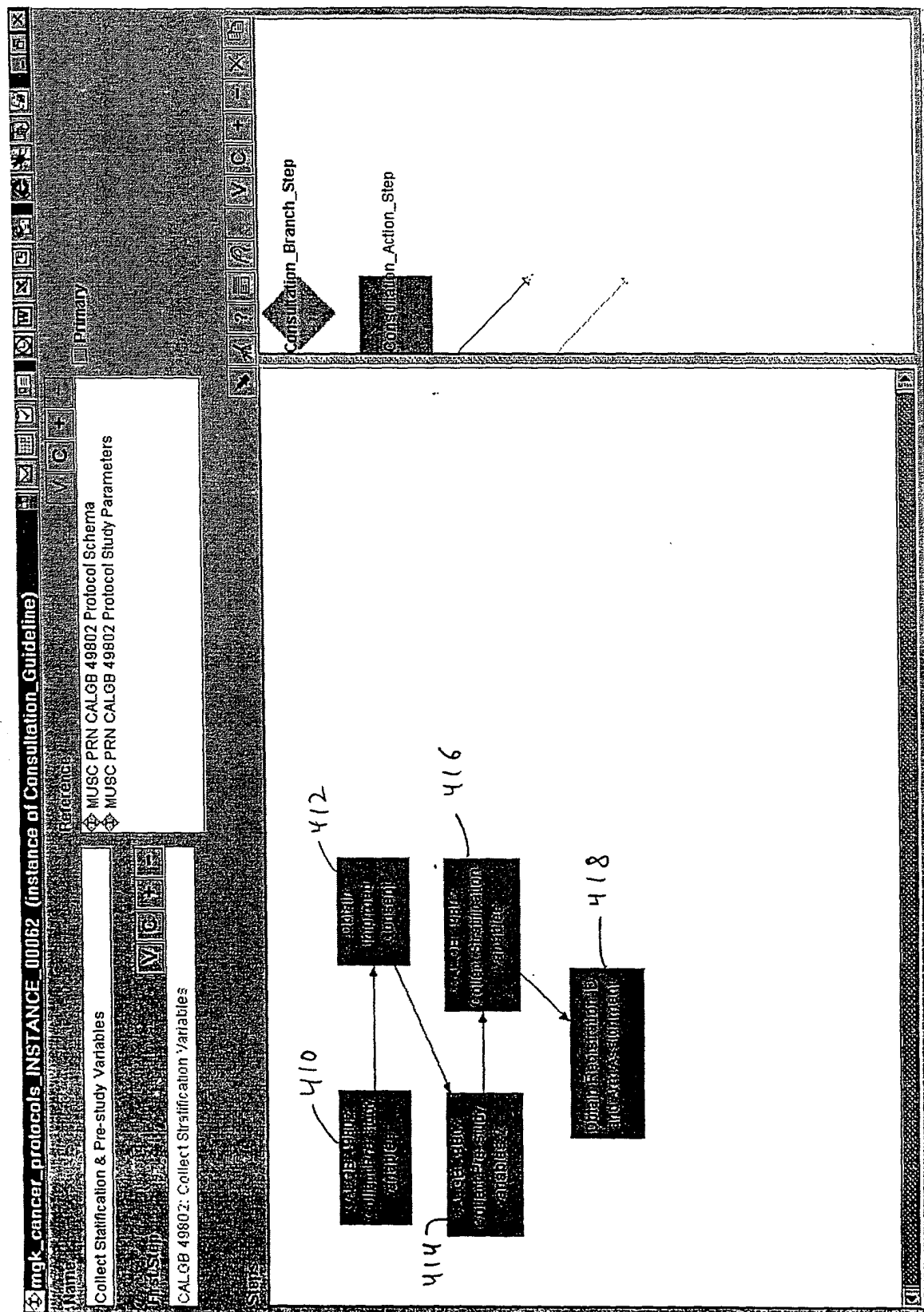



Fig. 4

mgk_cancer_protocols_INSTANCE_00063 (instance of Consultation_Act... [icon] [icon] [icon]

mgk_cancer_protocols_INSTANCE_00063 (instance of Consultation_Act...)

CALGB 49802: Collect Stratification Variables

Followed by [V] [C] [+]

Rule-1 [V] [C] [+]

Rule-2 [V] [C] [+]

Evaluate lymph node status

Evaluate menopausal status

Evaluate estrogen receptor status

Evaluate progesterone receptor status

References [V] [C] [+]

Fig. 5

614 2014/06/06

612

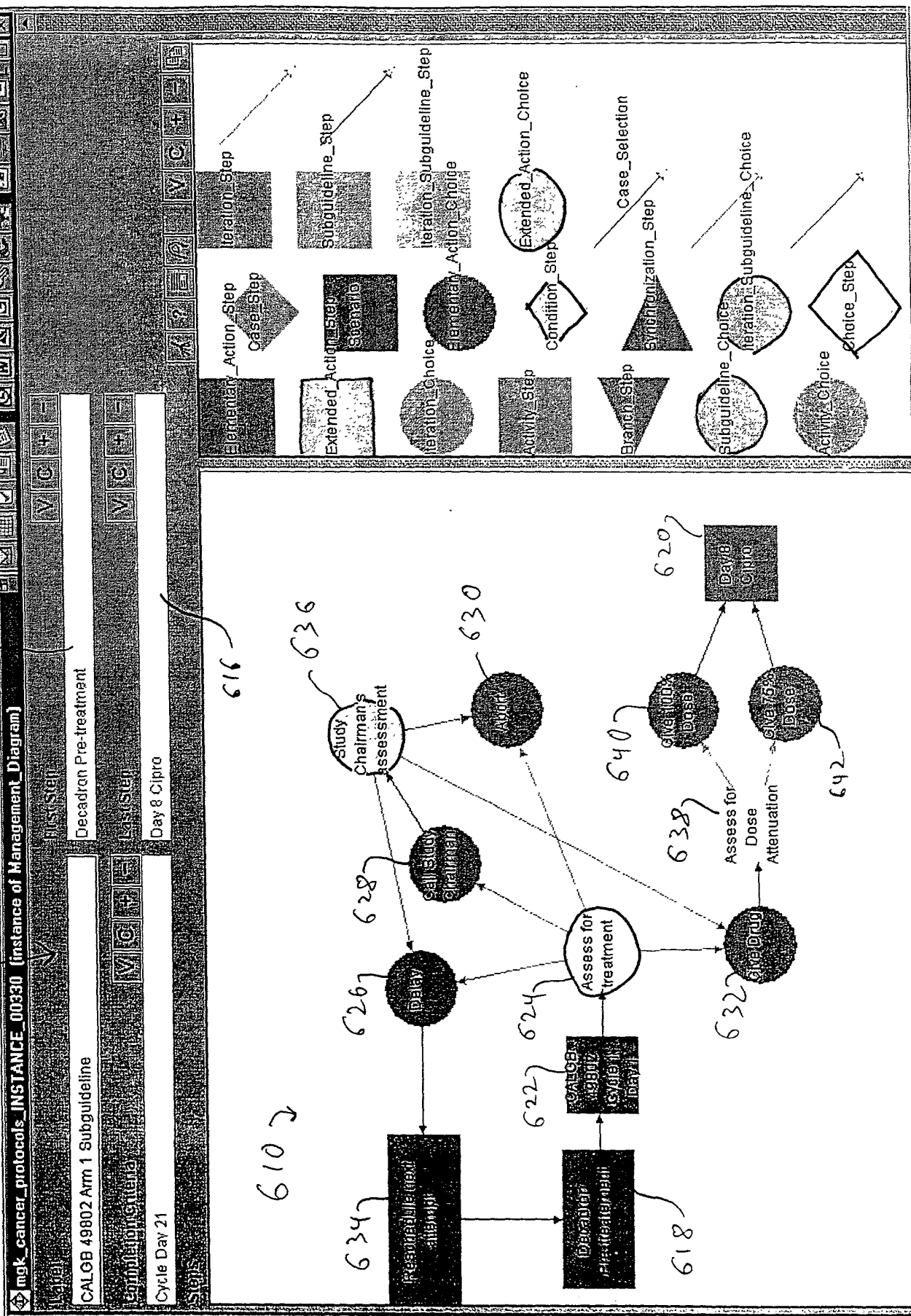


Fig. 6

724

mgk_cancer_protocols_INSTANCE_00575 (Instance of Management_Diagram)

710

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726

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760

762

764

766

768

770

772

774

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778

780

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784

786

788

790

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822

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836

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840

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844

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848

850

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864

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868

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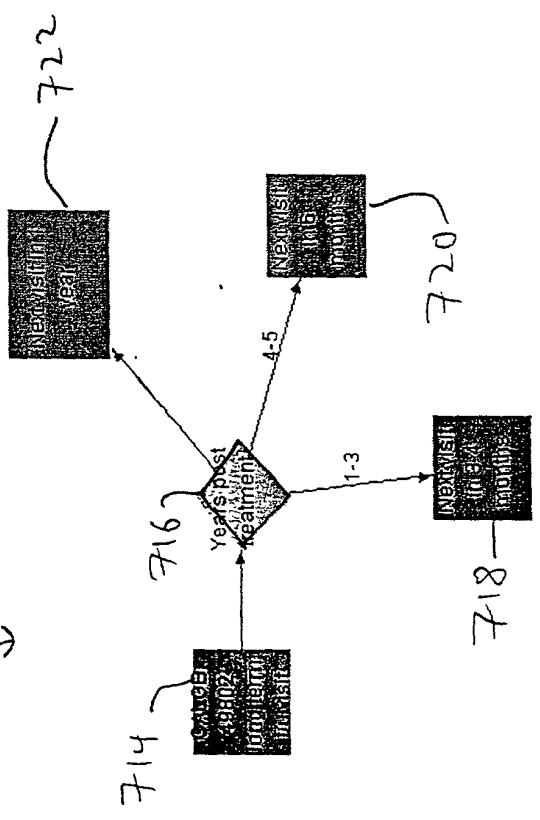


Fig. 7

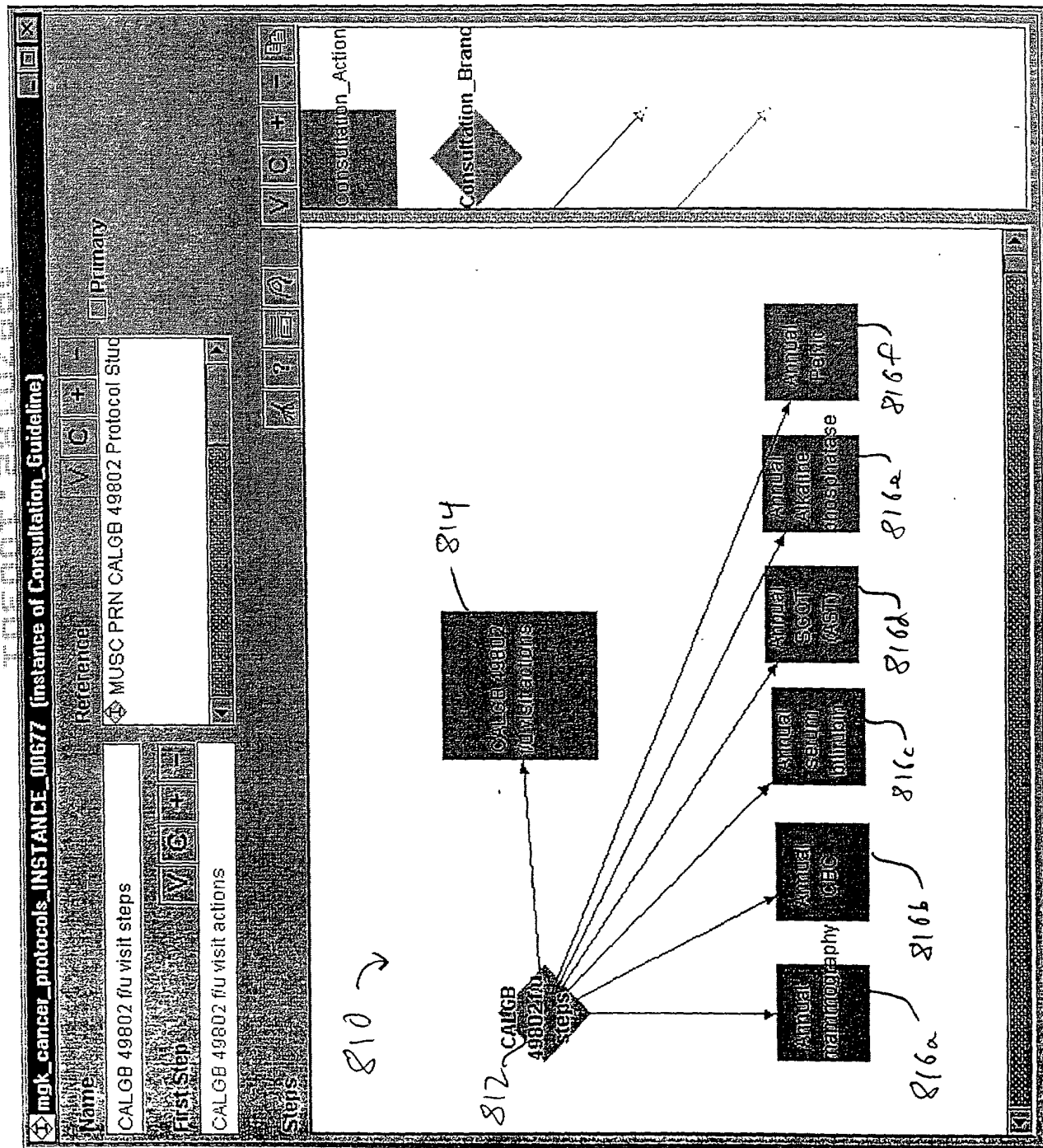


Fig. 8

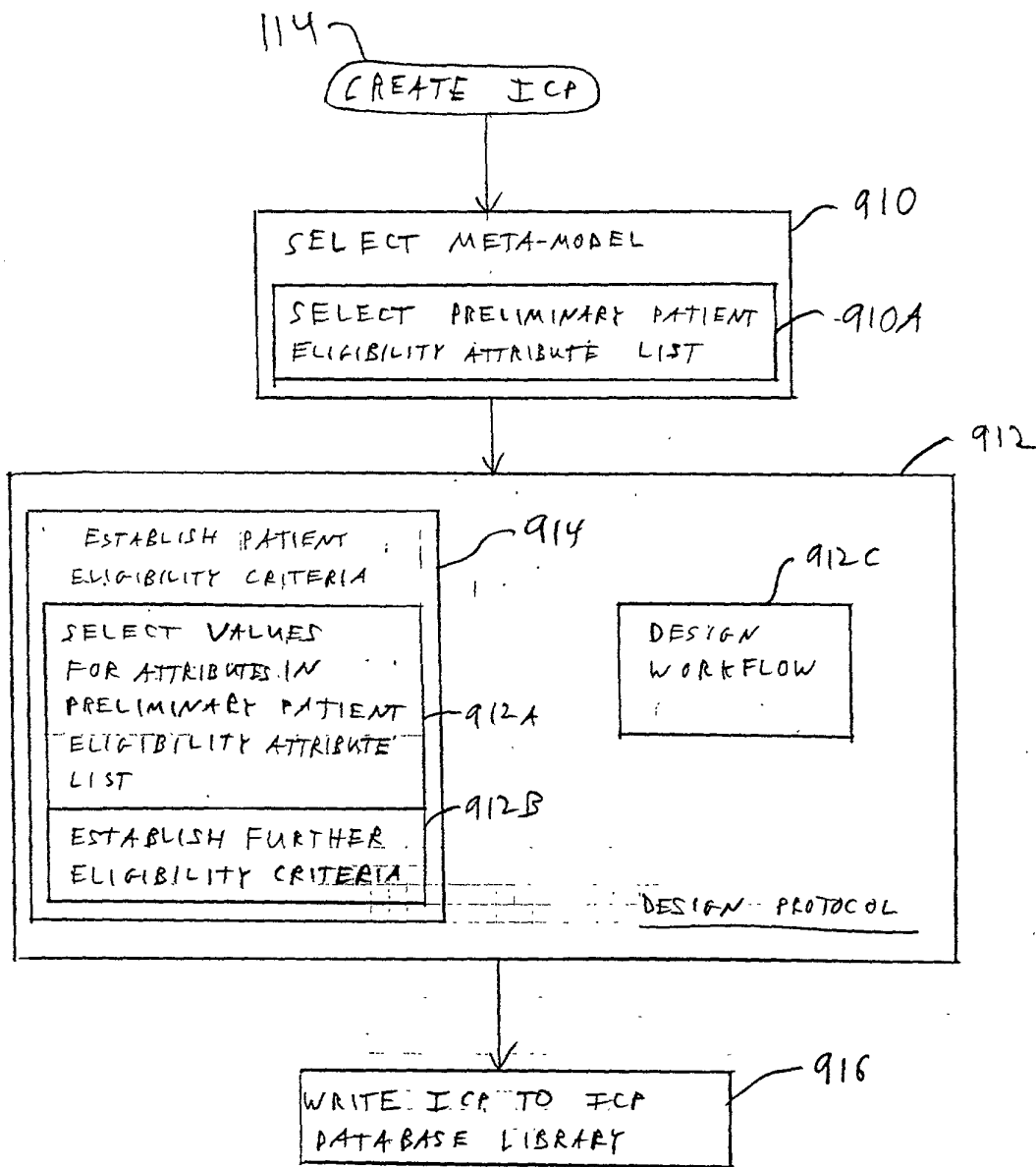


Fig. 9

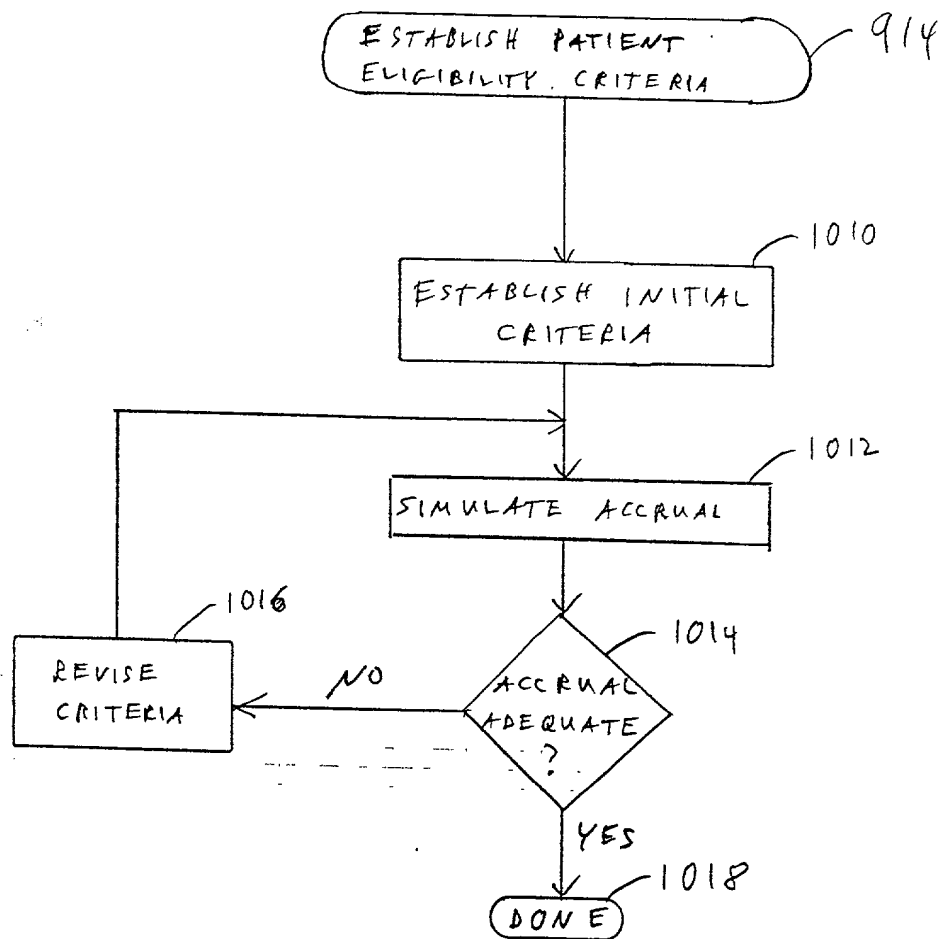


Fig. 10

FastTrack Protocol Protégé-2000 (C:\My Documents\Latest FastTrack HDF + CALGB 9840V\FastTrack Protocol.ppt)

Project Edit Window Help

Classes Form Instances

Protocol

1126

1112

1124

1130

1116

1128

1132

1150

1152

1154

1110

1118

1114

Fig. 11

FastTrack Protocol_INSTANCE_00212 (instance of Protocol)	
ProtocolTitle	Version
A Phase III Study of Paclitaxel via Weekly 1-Hour Infusion v	Update #1
ProtocolIdentifier	VersionDate
CALGB 9840	December 15
OfficialSourceDocument	EligibilityCriteriaSet
http://pm.musc.edu/research/protocol/deptmed/divhnc/bn	V C + -
ShortDescription	CALGB 9840 Eligibility Criteria 1212
CALGB 9840	
StudyChair	
Andrew D. Seidman, M.D.	
Sponsor	
CALGB	
QuickScreenCriterion	
Breast Cancer	
ProtocolObjectives	
To compare "standard" (S) paclitaxel at 175 mg/m ² via 3-hour infusion every 3 weeks to "dose-dense" (DD) paclitaxel at 80 mg/m ² via 1-hour infusion every week	
TrialStatus	FirstVisit
Active	Screening Visit
Open for accrual	V C + -
TrialPhase	ProtocolSchemaDiagram
Phase III	CALGB 9840 Schema
Cooperative group	V C + -

Fig. 12

1214

1210

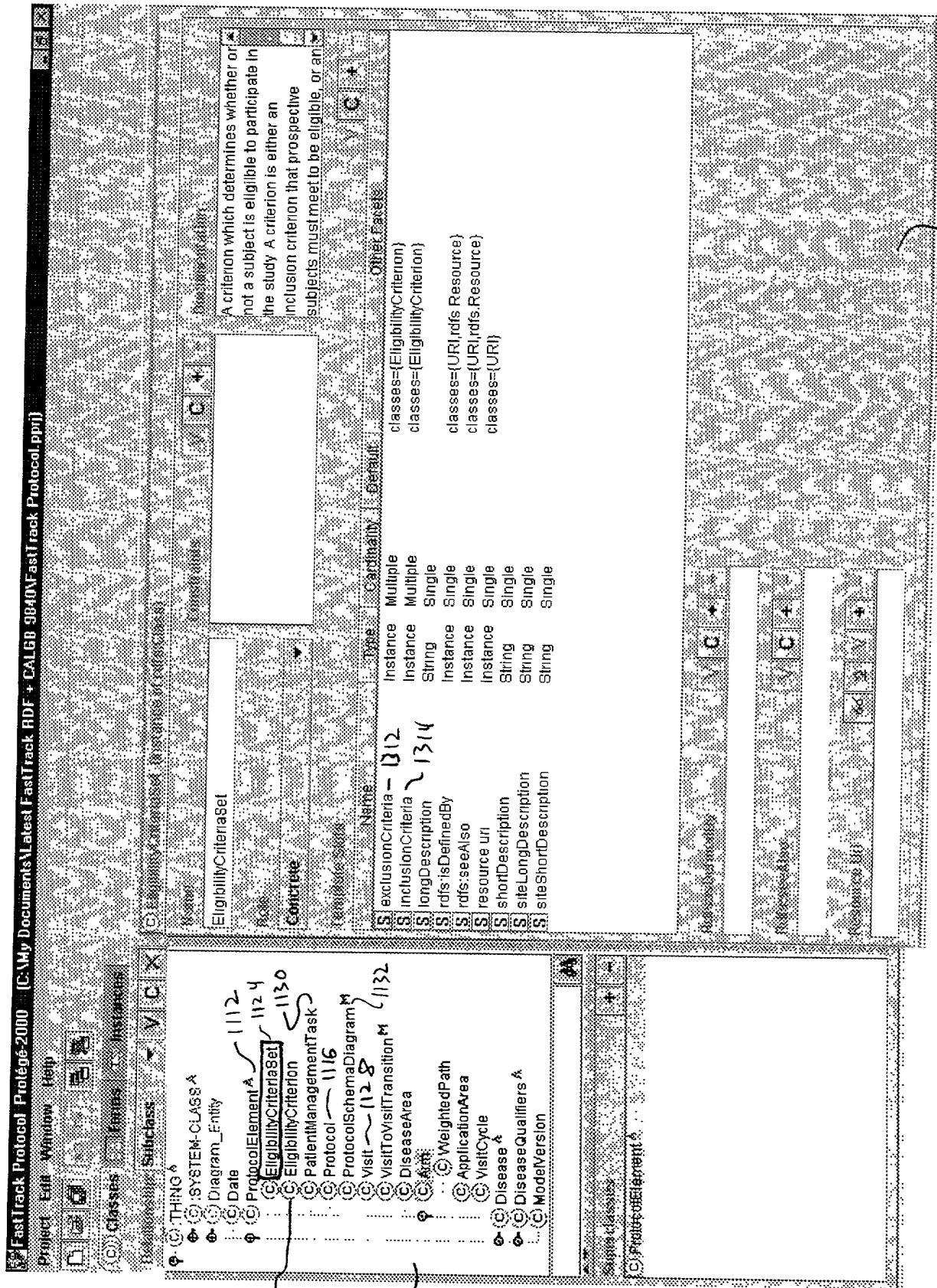


Fig. 13

FastTrack Protocol Protégé-2000 (C:\My Documents\Latest FastTrack RDF + CALGB 9840V\FastTrack Protocol.ppt)

Project Edit Window Help

Classes **Entities** **Instances**

Relationship: Subclass

- THING^A
- SYSTEM-CLASS^A
- Diagram_Entity
- Date
- ProtocolElement^A 1112
- EligibilityCriteriaSet 1124
- EligibilityCriterion 1130
- PatientManagementTask
- Protocol 1116
- ProtocolSchemaDiagram^M
- Visit 1128
- VisitToVisitTransition^M 1132
- DiseaseArea
- App^M
- WeightedPath
- ApplicationArea
- visitCycle
- Disease^A
- DiseaseQualifiers^A
- ModelVersion

EligibilityCriterion (Instance of rdfs:Class)

Name Eligibility-Criterion

Role Concrete

Constraints

Documentation
A criterion which determines whether or not a subject is eligible to participate in the study. A criterion is either an inclusion criterion that prospective subjects must meet to be eligible, or an exclusion criterion that prospective subjects must not meet to be eligible.

Template Slots

Name	Type	Cardinality	Default	Other Facets
S longDescription	String	Single		
S rdfs:isDefinedBy	Instance	Single		classes={URI,rdfs:Resource}
S rdfs:seeAlso	Instance	Single		classes={URI,rdfs:Resource}
S resource uri	Instance	Single		classes={URI}
S shortDescription	String	Single		
S siteLongDescription	String	Single		
S siteShortDescription	String	Single		

RDFS:isDefinedBy

RDFS:seeAlso

Resource Uri

Fig. 14

1410

FastTrack Protocol_INSTANCE_00074 (Instance of EligibilityCriteriaSet)

ShortDescription

CALGB 9840 Eligibility Criteria

InclusionCriteria

- Female
- Breast adenocarcinoma that is inoperable, recurrent, or metastatic
- More than 4 weeks since last chemotherapy
- More than 6 weeks since treatment with nitrosureas, melphalan, or
- More than 4 weeks since last hormonal therapy OR tumor measur
- Age >= 18
- Measurable disease
- Granulocytes >= 1,500 / ul
- Platelet count >= 100,000 / ul
- Creatinine <= 2.0 mg/dl
- Bilirubin within institutional normal limits
- SGOT (AST) <= 3X upper limits of normal
- Greater than 2 weeks from prior surgery

ExclusionCriteria

- More than 1 prior chemotherapy regimens for metastatic or locally
- CNS metastases if untreated or symptomatic
- Prior taxane for metastatic or locally-advanced breast cancer
- Prior taxane in adjuvant setting where patient remained disease fr
- Leptomeningeal carcinoma

LongDescription

SiteLongDescription

SiteShortDescription

RefIsDefinedBy

RefIsSeeAlso

Resource Uri

Fig. 15

FastTrack Protocol_INSTANCE_00073 [Instance of EligibilityCriterion]	
ShortDescription	CNS metastases if untreated or symptomatic
LongDescription	Patients with central nervous system metastases are eligible only if the patient has completed cranial irradiation at least 6 months prior, is currently asymptomatic, and is not currently receiving corticosteroids for this condition.
SiteLongDescription	
SiteShortDescription	

The screenshot displays the Protege software interface, which is used for creating and editing ontologies. The interface is divided into several panes:

- Top Pane (Class Hierarchy):** Shows a tree of classes. The 'Visit' class is highlighted, and its subclasses are listed: 'EligibilityCriteriaSet', 'EligibilityCriteria', 'PatientManagementTask', 'Protocol', 'ProtocolSchemaDiagram', 'VisitToVisitTransition', 'DiseaseArea', 'Aim', 'WeightedPath', 'ApplicationArea', 'VisitCycle', 'Disease', 'DiseaseQualifiers', and 'ModelVersion'.
- Left Pane (Class Information):** Provides details for the selected 'Visit' class. It includes:
 - Name:** Visit
 - Role:** Concrete
 - Template Slots:** A list of slots with their types and cardinalities:
 - dataManagementTasks: Instance, Multiple
 - longDescription: String, Single
 - patientManagementTasks: Instance, Multiple
 - possibleVisitTransitions: Instance, Multiple
 - rdfs:isDefinedBy: Instance, Single
 - rdfs:seeAlso: Instance, Single
 - resource uri: Instance, Single
 - shortDescription: String, Single
 - siteLongDescription: String, Single
 - siteShortDescription: String, Single
 - Constraints:** A section for defining constraints on the class.
 - Documentation:** A text area for providing documentation for the class.
- Right Pane (Instance Information):** Provides details for the selected instance. It includes:
 - Name:** Visit
 - Role:** Concrete
 - Template Slots:** A list of slots with their types and cardinalities:
 - dataManagementTasks: Instance, Multiple
 - longDescription: String, Single
 - patientManagementTasks: Instance, Multiple
 - possibleVisitTransitions: Instance, Multiple
 - rdfs:isDefinedBy: Instance, Single
 - rdfs:seeAlso: Instance, Single
 - resource uri: Instance, Single
 - shortDescription: String, Single
 - siteLongDescription: String, Single
 - siteShortDescription: String, Single
 - Constraints:** A section for defining constraints on the instance.
 - Documentation:** A text area for providing documentation for the instance.

The 'Visit' class is defined as a concrete class. The 'VisitToVisitTransition' class is defined as a subclass of 'Visit'. The 'VisitToVisitTransition' class is defined as a subclass of 'Visit'. The 'VisitToVisitTransition' class is defined as a subclass of 'Visit'.

Fig. 17

0171

FastTrack Protocol_INSTANCE_00014 (Instance of Visit)	
ShortDescription Arm A Treatment Visit	Possible Visit Transitions Arm A Treatment to Arm A Treatment Retry #1 Arm A Treatment to Long Term Followup Arm A Treatment Visit to Arm A Treatment Visit
Data Management Tasks Submit Form C-116 Submit Form C-118 Submit Form C-080 Submit Form C-344 + Form C-080 (*) Submit Form C-344 + Form C-272 (*) Submit Form C-113 (*) Submit Form C-260 (*) Submit Form C-300 (*)	Patient Management Tasks Confirm no G-CSF given in past 24 hours Give Dexmethosone 10 mg IV, 30 minutes Give Diphenhydramine 50 mg IV, 30 minutes Give Cimetidine 300 mg IV, 30 minutes Give anti-emetics (*) Give Arm A Pacitaxel treatment Give G-CSF (*) Evaluate Patient Response Schedule next visit
LongDescription Arm A of the CALG 9840 consists of treatment with Paclitaxel 175 mg/m ² administered as a 3 hour infusion intravenously every three weeks. One cycle is equivalent to one infusion. Treatment cycles will be repeated every 21 days as long as the patient has stable or responding disease. Granulocyte count must be $\geq 1500/\mu\text{l}$ and platelet count must be $\geq 100,000/\mu\text{l}$ on day 1 of each cycle. Patients should receive a minimum of two cycles of therapy, unless there is rapid disease progression ($>50\%$ increase in product of bi-dimensional measurements).	
Site LongDescription	
Site ShortDescription	

Fig. 18

The screenshot displays the Protegé-2000 software interface for editing the 'FastTrack Protocol' project. The left-hand pane shows a class hierarchy under 'Relationships', with 'Protocol' (class 1116) selected. The right-hand pane provides detailed information for the 'ManagementTask' class (class 1124). This pane includes tabs for 'Name', 'Constraints', 'Documentation', and 'Other Facets'. The 'Documentation' tab is currently active, displaying a description of the task. Below the tabs, a table lists various facets and their values, such as 'longDescImportance' (Symbol), 'longDescription' (String), and 'rdf:isDefinedBy' (Instance). At the bottom of the right pane, there are input fields for 'Rdfs:isDefinedBy', 'Rdfs:seeAlso', and 'Resource Uri', each with associated control buttons. The bottom status bar indicates the current class is 'Protocol'.

ShortDescription

Give Arm A Paclitaxel treatment

LongDescription

Give Pacifitaxel 175 mg/m² IV, 3 hours. This treatment is given to patients in Arm A of the CALGB 9840 protocol. It is given once every 3 weeks. One cycle is equivalent to one infusion. Granulocyte count must be $\geq 1500/\mu\text{l}$ and platelet count must be $\geq 100,000/\mu\text{l}$ on day 1 of each cycle in order to proceed with the Pacifitaxel infusion. Patients must receive the pre-medication prior to Pacifitaxel infusion. If either the granulocyte or platelet count are not adequate, do not continue with treatment. Patients should receive a minimum of 2 cycles unless there is rapid disease progression.

Expected toxicities:

Dose Modifications:

SiteLongDescription

Fig. 20

FastTrack Protocol_INSTANCE_00196 (Instance of ManagementTask)	
ShortDescription	Submit Form C-116
LongDescription	Submit CALGB Advanced Breast Cancer Followup-form (C-116) every two cycles while on protocol therapy, at 6 & 12 months after end of treatment, at disease progression or initiation of non-protocol therapy.
SiteLongDescription	
SiteShortDescription	

Fig. 21

Project Edit Window Help

Classes

Relationship: Subclass

THING

SYSTEM-CLASS A

Diagram_Entity

Dale

ProtocolElement A

EligibilityCriteriaSet

EligibilityCriterion

PatientManagementTask

Protocol

ProtocolSchemaDiagram

Visit

VisitToVisitTransition

DiseaseArea

WeightedPath

ApplicationArea

VisitCycle

Disease A

DiseaseQualifiers A

ModeVersion

1126

1110

1112

1124

1130

1116

1128

1132

2210

VisitToVisitTransition (Instance of Connector Metaclass)

Name

VisitToVisitTransition

Role

Concrete

Constraints

Documentation

A one-way link between a source visit (first_object) and a target visit (second_object). The inherited descriptions specify guidance about when/how/why to make this transition.

Template Slots

Name	Type	Cardinality	Default	Other Facets
first_object	Instance	Single		classes={URI,rdfs:Resource}
longDescription	String	Single		classes={URI,rdfs:Resource}
maximumRelativeTime	String	Single	-2218	classes={URI}
minimumRelativeTime	String	Single	-2220	classes={URI}
preferredRelativeTime	String	Single	-2222	classes={URI}
rdfs:isDefinedBy	Instance	Single		
rdfs:seeAlso	Instance	Single		
resource url	Instance	Single		
second_object	Instance	Single		
shortDescription	String	Single		
siteLongDescription	String	Single		
siteShortDescription	String	Single		

First Object Slot Pointer

Second Object Slot Pointer

Rdfs:isDefinedBy

Rdfs:seeAlso

Fig. 22

2212

FastTrack Protocol_INSTANCE_00023 (instance of VisitToVisitTransition)

ShortDescription		PreferredRelativeTime
Arm A Treatment to Arm A Treatment Retry #		7
First Object	V C + -	MaximumRelativeTime
Arm A Treatment Visit		7
Second Object	V C + -	MinimumRelativeTime
Arm A Treatment Retry #1		7
LongDescription		
<p>If either granulocyte or platelet count are not adequate, blood counts should be repeated weekly and treatment should be instituted when there has been hematologic recovery. Patients receiving G-CSF are not eligible for re-treatment unless they have been off G-CSF for a minimum of 24 hours.</p>		
SiteLongDescription		<input checked="" type="checkbox"/> Is Preferred Transition
SiteShortDescription		

18187

2310

Fig. 23

FastTrack Protocol Protégé-2000 (C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.ppt)

Project Edit Window Help

Relationship Subclass Instances

Classes: **ProtocolSchemaDiagram** (Instance of Network Metaclass)

Relationships:

- ProtocolSchemaDiagram (1116)
 - ProtocolElement (1124)
 - EligibilityCriteriaSet (1130)
 - PatientManagementTask (1132)
 - Protocol (1116)
 - ProtocolSchemaDiagram (1116)
 - Visit (1128)
 - VisitToVisitTransition (1132)
 - DiseaseArea (2210)
 - WeightedPath (1110)
 - ApplicationArea (1110)
 - VisitCycle (1110)
 - Disease (1110)
 - DiseaseQualifiers (1110)
 - ModelVersion (1110)

ProtocolSchemaDiagram (Instance of Network Metaclass)

Name: ProtocolSchemaDiagram

Role: Concrete

Constraints: V C + -

Documentation: The ProtocolSchemaDiagram is the part of the protocol which details the design of the trial. A protocol schema's first visit is always at least one screening visit, which is assumed

Template Slots:

| Name | Type | Cardinality | Default | Other Facets |
|-----------------------|----------|-------------|---------|----------------------------------|
| connectors | Instance | Multiple | | classes=(VisitToVisitTransition) |
| diagramNodes | Instance | Multiple | | classes=(Visit) |
| last_divider_location | Integer | Single | | |
| layout_information | Instance | Multiple | | classes=(ObjectLocation) |
| longDescription | String | Single | | |
| main_panel_height | Integer | Single | | |
| main_panel_width | Integer | Single | | |
| rdfs:isDefinedBy | Instance | Single | | classes=(URI,rdfs.Resource) |
| rdfs:seeAlso | Instance | Single | | classes=(URI,rdfs.Resource) |
| resource uri | Instance | Single | | classes=(URI) |
| shortDescription | String | Single | | |
| siteLongDescription | String | Single | | |
| siteShortDescription | String | Single | | |

Node Slot: V C + -

DiagramNodes

Rdfs:isDefinedBy: V C + -

Rdfs:seeAlso: V C + -

Fig. 24

Fig. 25

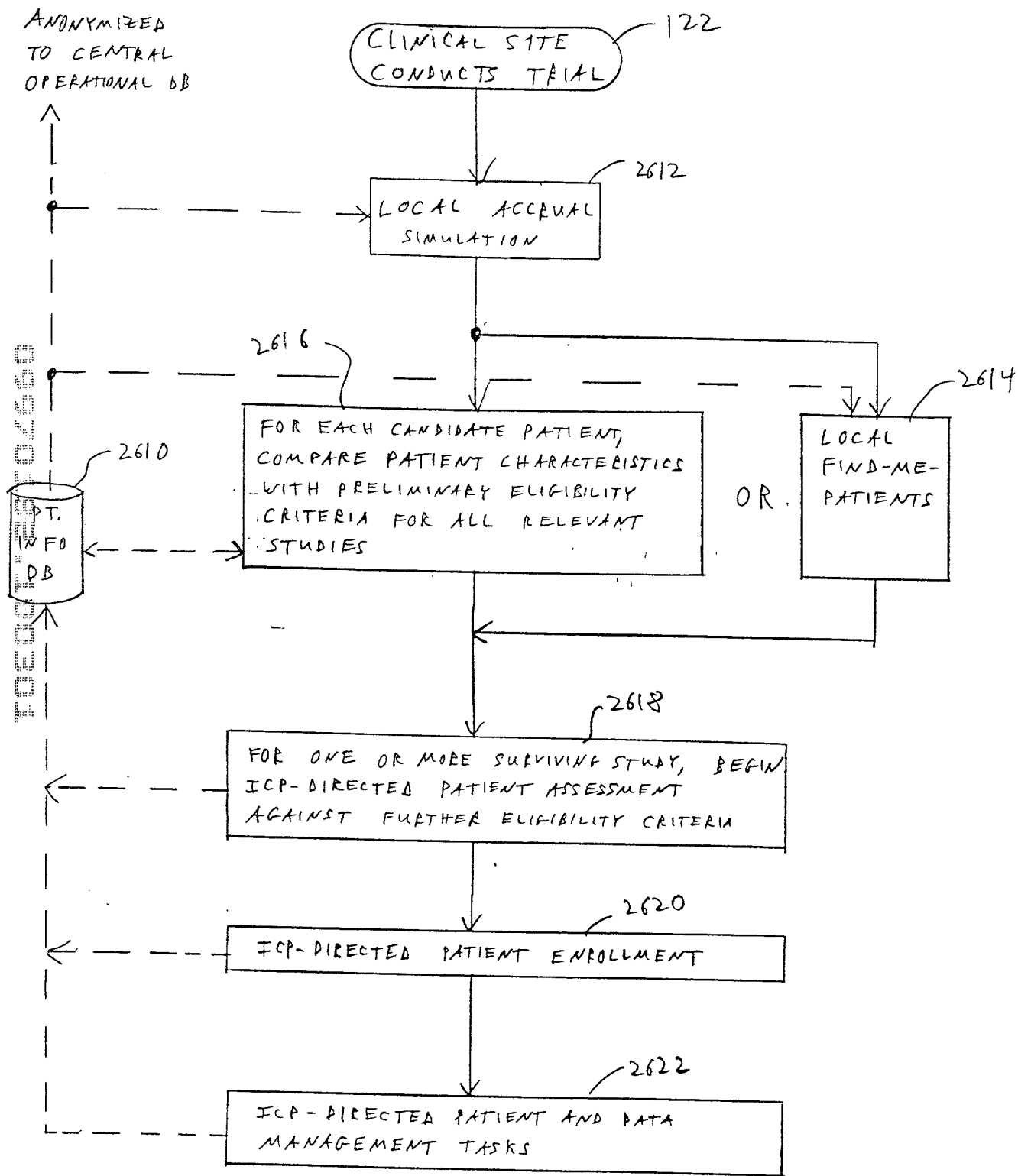


Fig. 26

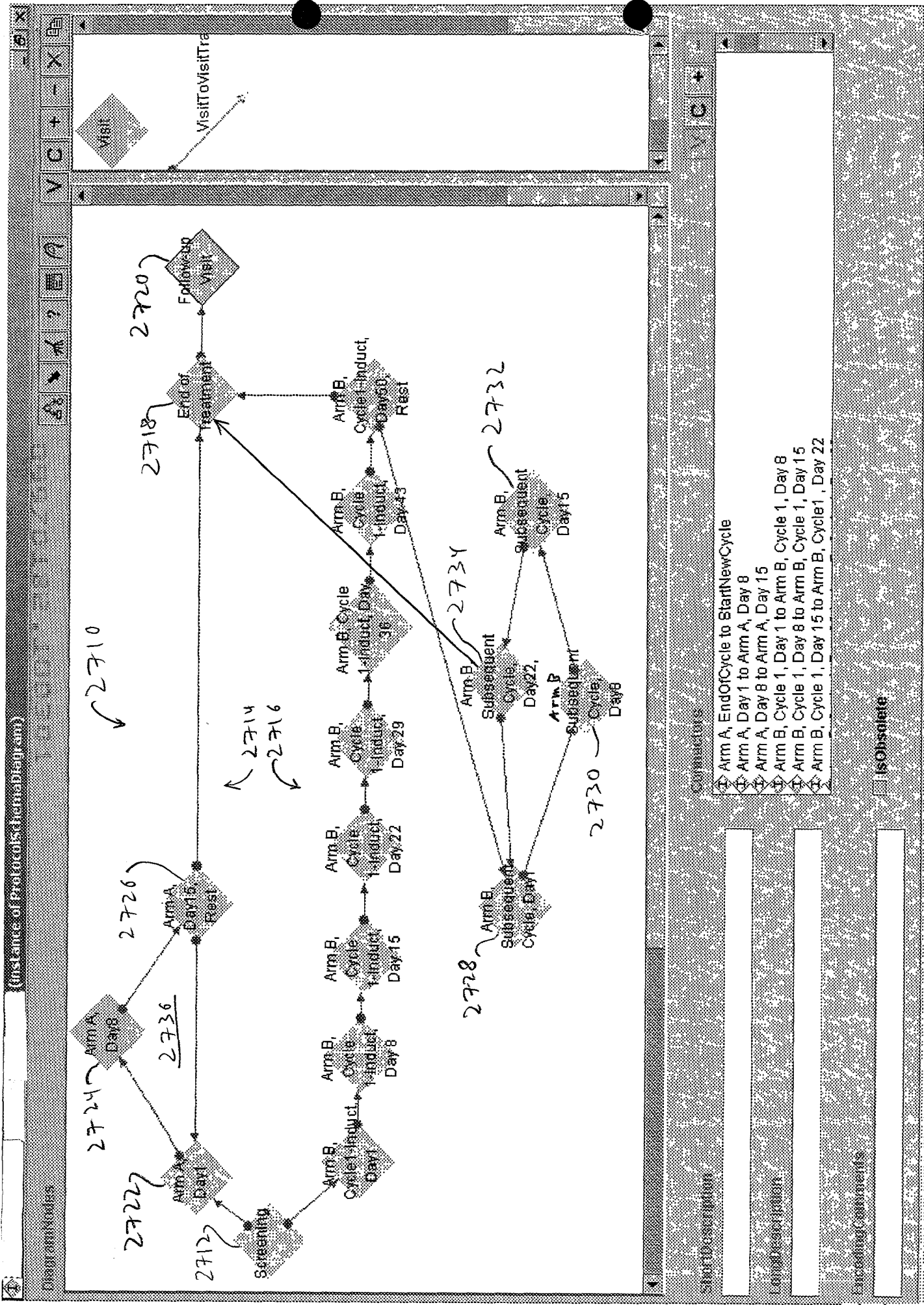


Fig. 27

Fi. 28

[Instance of Arm]

| | |
|---|---|
| <p>ShortDescription</p> <p>Arm A ~ 2710</p> <p>LongDescription</p> <p>Arm A: Gemcitabine and Irinotecan HCl (OPT-11)</p> | <p>Encoding Comments</p> <p>Editorial change</p> |
| <p>Visits</p> <p>Screening ~ 2712</p> <p>Arm A, Day 1 ~ 2712</p> <p>Arm A, Day 8 ~ 2724</p> <p>Arm A, Day 15, Rest ~ 2726</p> <p>End of Treatment ~ 2718</p> <p>Follow-up Visit ~ 2720</p> | <p>Obsolete Visits</p> |

☐ IsObsolete
☐ DrillDown

Fig. 29

Fig. 30

3110

(instance of WeightedPath)

| ShortDescription | Visits |
|-------------------------------------|---|
| Arm A Path | Screening ~ 2712
Arm A Cycle ~ 2736
End of Treatment ~ 2718
Follow-up cycle ~ 2720 |
| LongDescription | |
| EnrollingComments | |
| <input type="checkbox"/> IsObsolete | <input type="checkbox"/> DrillDown |
| | PathWeight: 1 |

Fig. 31

Fig. 32

3210

2736

| [Instance of VisitCycle] | |
|------------------------------------|--|
| ShortDescription | VisitCycle |
| Arm A Cycle | Arm A, Day 1 ~ 2722
Arm A, Day 8 ~ 2724
Arm A, Day 15, Rest ~ 2726 |
| LongDescription | |
| Executing Commands | CycleCount |
| <input type="checkbox"/> DrillDown | <input type="checkbox"/> IsIsolate |
| | 3 |

Fig. 33

Timeline Simulation Process Flow

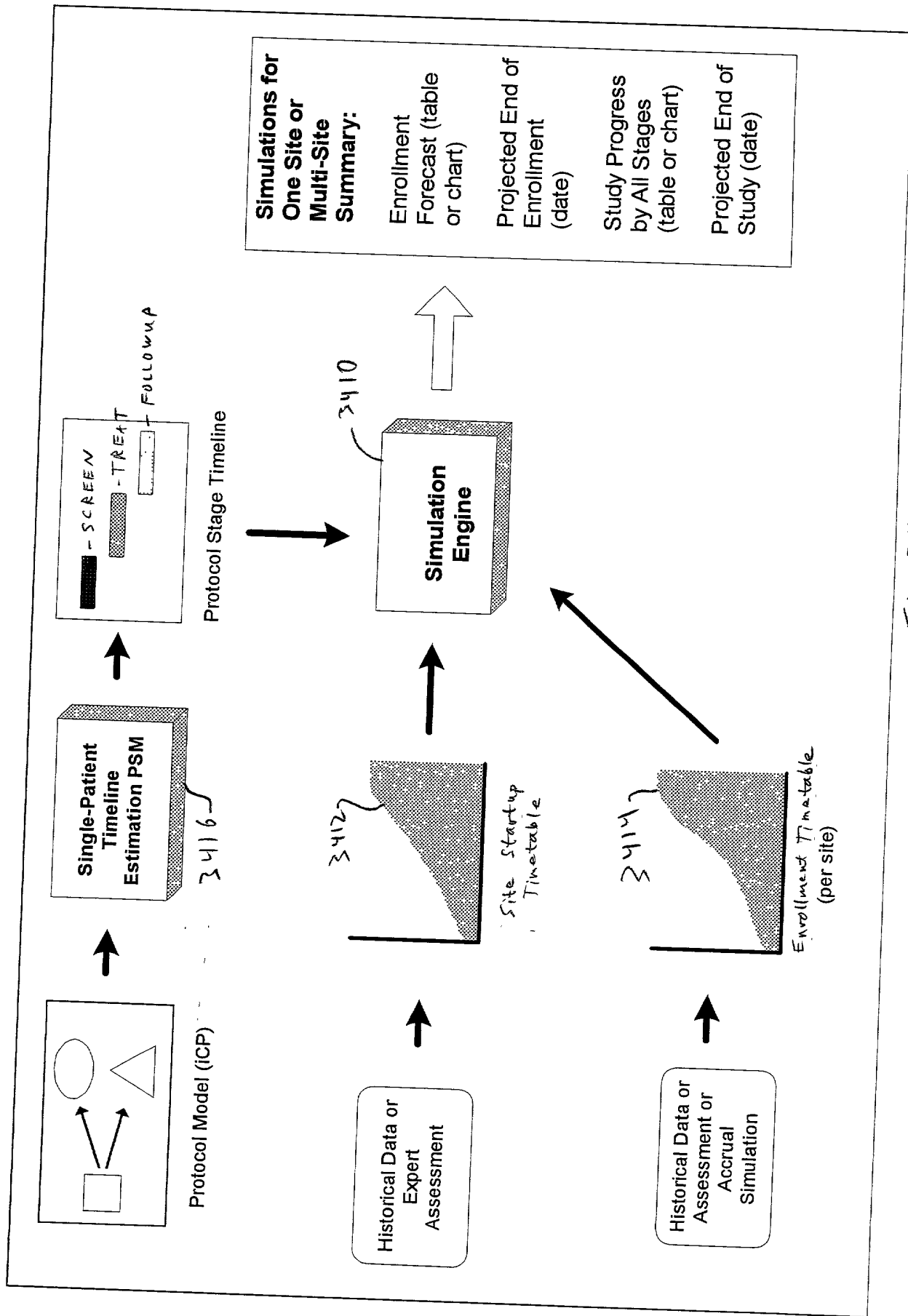


Fig. 34

CALCULATE PROTOCOL STAGES DURATION

3510
COLLECT ALL Weighted Path OBJECTS
IN THE ICA

3512
LOOP THROUGH ALL Weighted Path
OBJECTS

3514
CALCULATE DURATION OF
CURRENT Weighted Path

3516
MORE
Weighted Paths
?
Yes

3518
NORMALIZE PATHS

3520
WRITE RESULTS TO
WEIGHTED AVERAGES FILE

END

Fig. 35

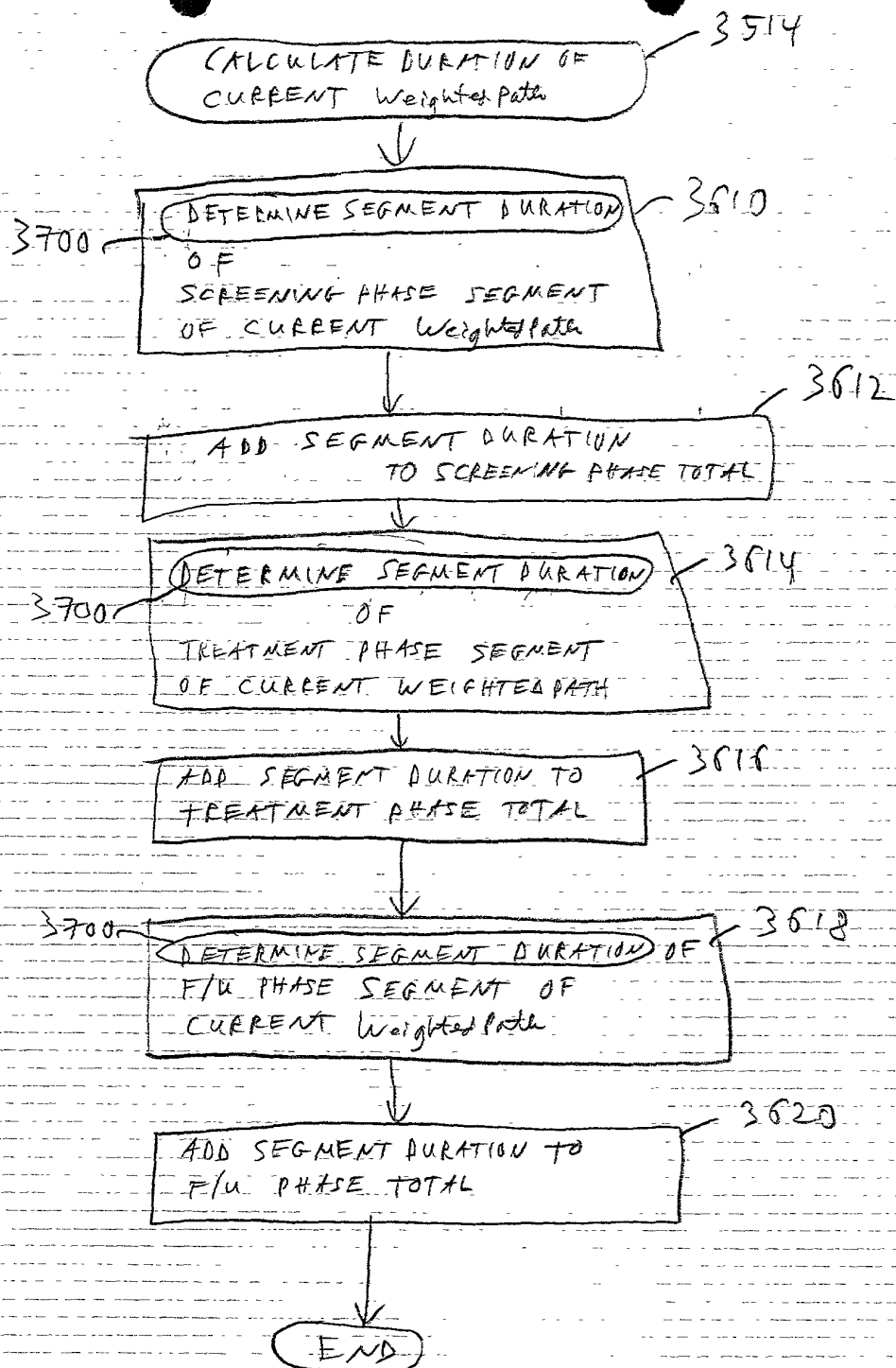


Fig. 36

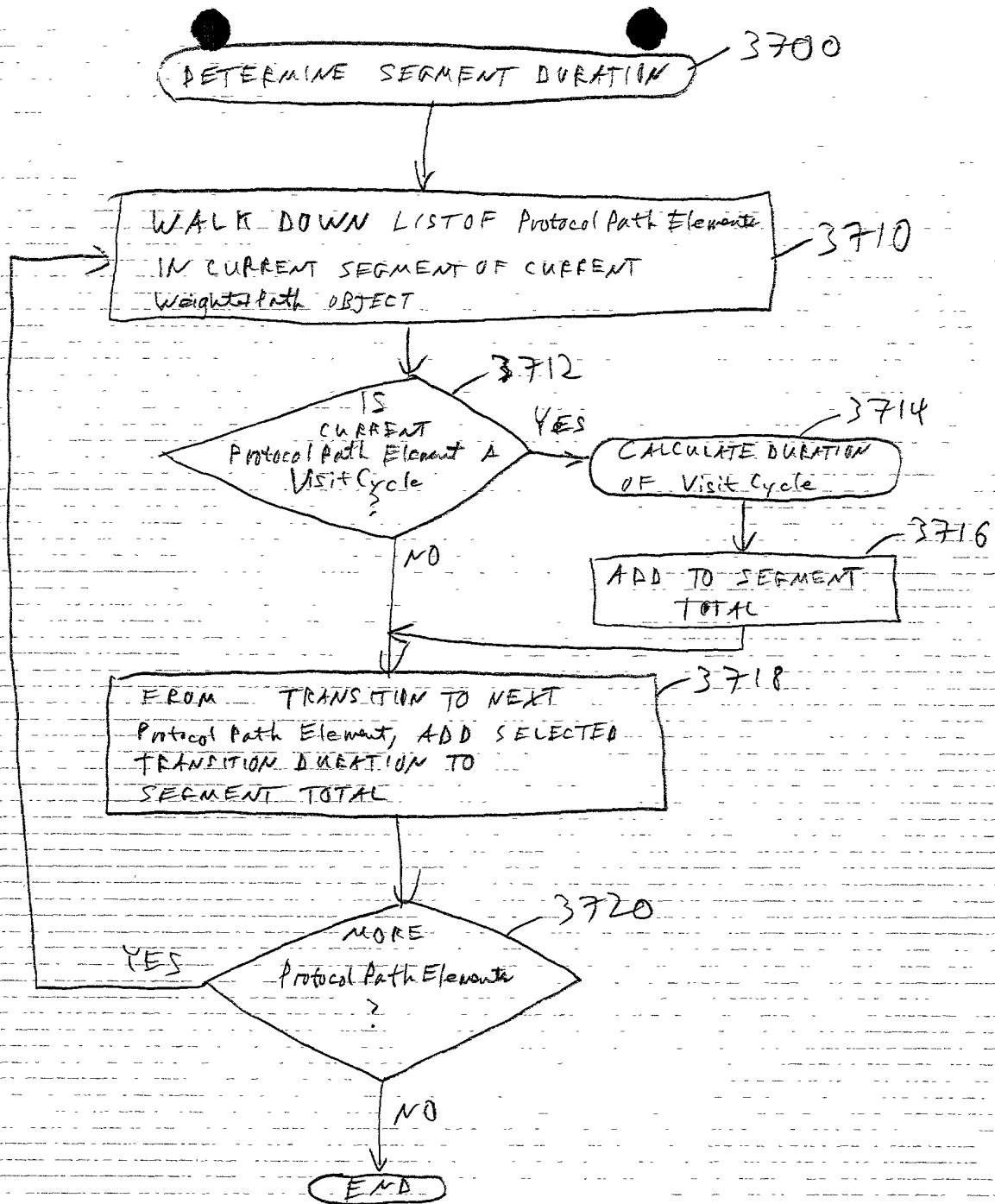


Fig. 37

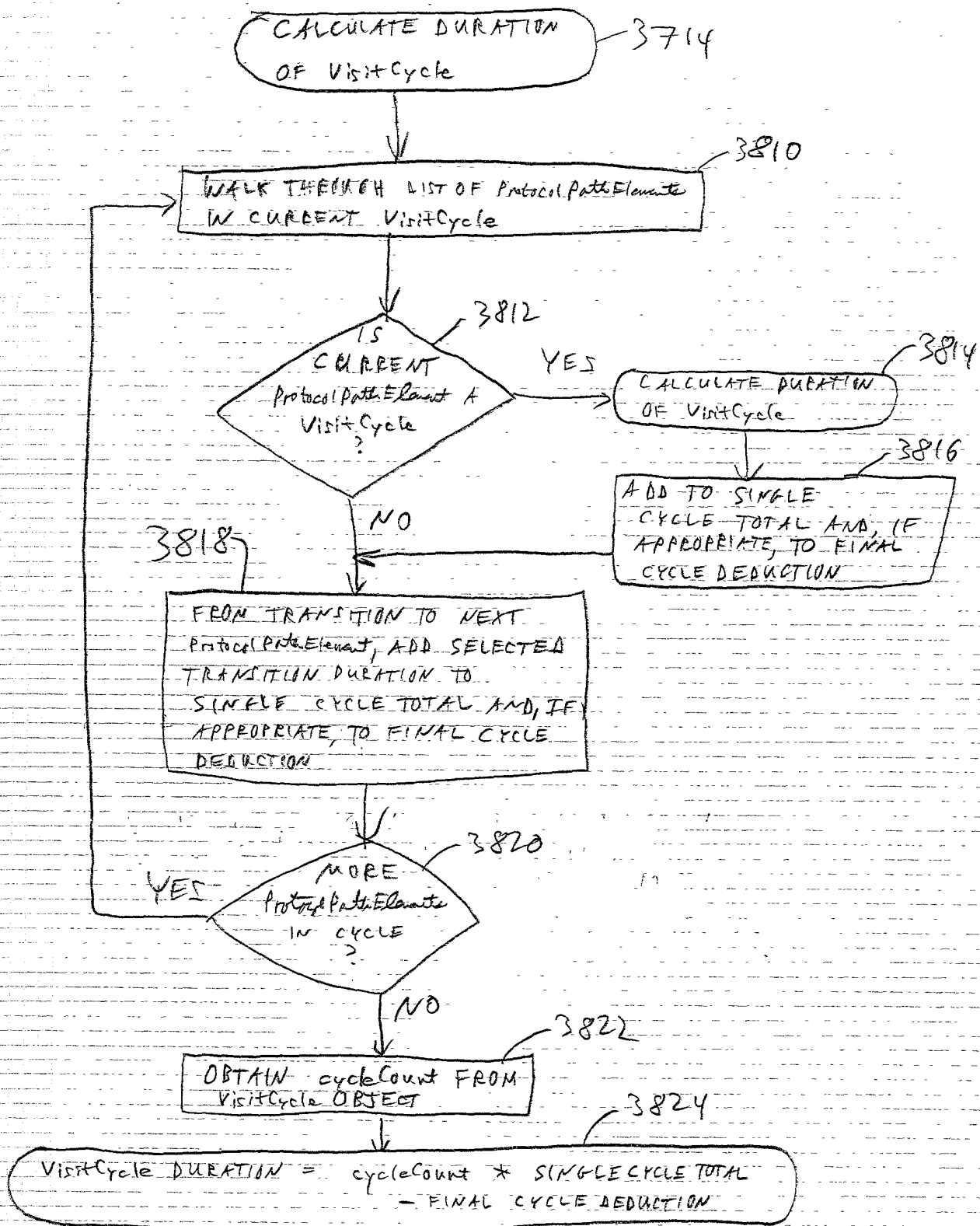


Fig. 38

Screening duration = $7 + 7 = 14$
 Treatment = $3 * (1 + 1 + 1) - 1 + 7 + 7 = 22$
 Follow up = 30

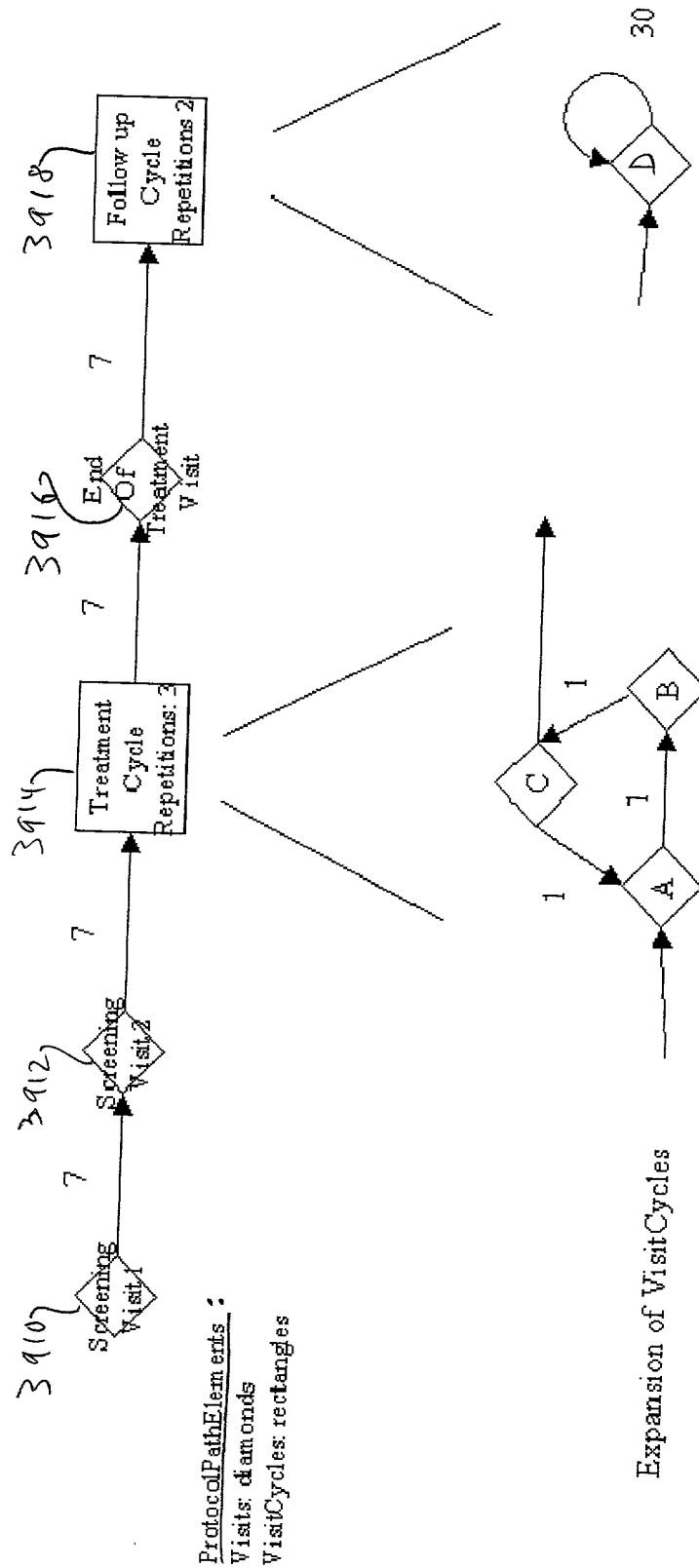
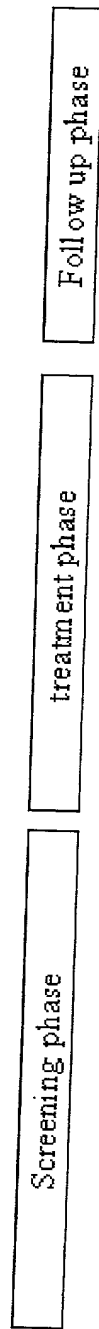


Fig. 39

[illegible]

;

Fig. 40